Document Information Page

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Linking Instructions:	If this is the first action on the application, link the outgoing letter to the initial submission, RS, AR, or FO coded incoming document for the supplement being acted on, as appropriate. Otherwise, the outgoing letter must be linked to the major amendment submitted in response to the previous action letter. In addition, the outgoing document should also be linked to all associated amendments and correspondences included in the action.

END OF DOCUMENT INFORMATION PAGE

The letter begins on the next page.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-560/S-036

Merck & Co., Inc.
Attention: Michele Flicker, M.D., Ph.D.
Director, Regulatory Affairs
P.O. Box 2000
Mail Drop: Ry 33-720
Rahway, NJ 07065

Dear Dr. Flicker:

Please refer to your supplemental new drug application dated February 15, 2002, received February 19, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Fosamax (alendronate sodium) Tablets.

We acknowledge receipt of your submission dated March 8, 2002.

This supplemental application, submitted as a "Supplement - Changes Being Effected" supplement, proposes alternative ("push-through" design) packaging to the currently approved 35 and 70 mg once weekly tablet 4-count trade bifold packaging ("peel-push" design). The "push-through" design blister is identical to the design of the approved 1-count sample package approved with supplements -021 and -022.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (text for the 35, and 70 mg strength 4-count trade bifold blister packages submitted February 15, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

Sheldon Markofsky, Ph.D.
Acting Chemistry Team Leader II, DNDC II for the
Division of Metabolic and Endocrine Drug Products
Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure

WEEK 1
Peel back strip
Important information:
Please read the enclosed Patient Information leaflet before taking Once Weekly FOSAMAX® (Alendronate Sodium Tablets). Keep this and all drugs out of the reach of children. Store at room temperature, 15–30°C (59–86°F).
ONCE WEEKLY
FOSAMAX®
(alendronate sodium tablets)
WEEK 2
Peel back strip
N 3 0006-0077-44 9
WEEK 3
Peel back strip
Apply Prescription Label Here
WEEK 4
Peel back strip
9508400
Once Weekly FOSAMAX® (Alendronate Sodium Tablets) 35 mg –No. 3813
For the prevention of osteoporosis in postmenopausal women
ONCE WEEKLY
FOSAMAX®
(Alendronate Sodium Tablets)
35 mg
Osteoporosis is a disease that causes bones to become thin, weak, and easy to break
That's why it is important you take Once Weekly FOSAMAX to help protect your bones.
Each tablet contains 45.68 mg alendronate sodium (35 mg free acid equivalent)
4 Tablets
No. 3813
Rx only
USUAL ADULT DOSAGE:
ONE 35 mg TABLET ONCE WEEKLY
See accompanying circular for complete dosage information.
MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA

How to take Once Weekly FOSAMAX® 35 mg

(Alendronate Sodium Tablets)

Choose the day of the week that best fits your schedule.
Every week, take one FOSAMAX tablet on your chosen day.

After getting up for the day on your chosen day of the week, swallow (do not chew or suck) one FOSAMAX tablet with a full glass (6–8 oz.) of plain water, on an empty stomach. Do not take FOSAMAX at bedtime or before arising for the day.

Begin your morning activities...but don't lie down, eat, drink, or take other medication for at least 30 minutes. If you want to lie down after 30 minutes, you must eat breakfast first.

Remember to take one FOSAMAX tablet once each week on that same day for as long as your doctor prescribes it.

If you miss a dose, take only one FOSAMAX tablet on the morning after you remember. *Do not take two tablets on the same day.* Return to taking one tablet once a week, as originally scheduled on your chosen day.

There is important additional information about how to take *Once Weekly* FOSAMAX in the enclosed Patient Information leaflet. Please read it carefully.

ONCE WEEKLY
FOSAMAX®
(alendronate sodium tablets)

9508300

Choose your day for taking Once Weekly FOSAMAX® 35 mg

(Alendronate Sodium Tablets)

Write in the best date for you to start FOSAMAX.

WEEK 1

SUNDAY
MONDAY
TUESDAY
WEDNESDAY
THURSDAY
FRIDAY
SATURDAY

WEEK 2

WEEK 3

WEEK 4

(Time to refill)

How to remove tablets:

1. Peel back strip on back.
2. Push tablet out from front.

For the treatment of osteoporosis in postmenopausal women
ONCE WEEKLY
FOSAMAX®
(Alendronate Sodium Tablets)
70 mg
Osteoporosis is a disease that causes bones to become thin, weak, and easy to break.
That's why it is important you take Once Weekly FOSAMAX to help protect your bones.
Each tablet contains 91.37 mg alendronate sodium (70 mg free acid equivalent)
4 Tablets
No. 3814
Rx only
USUAL ADULT DOSAGE:
ONE 70 mg TABLET
ONCE WEEKLY
See accompanying circular for complete dosage information.
MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA
Once Weekly FOSAMAX® (Alendronate Sodium Tablets) 70 mg –No. 3814
Important information:
Please read the enclosed Patient Information leaflet before taking Once Weekly FOSAMAX® (Alendronate Sodium Tablets). Keep this and all drugs out of the reach of children. Store at room temperature, 15–30°C (59–86°F).
ONCE WEEKLY
FOSAMAX®
(alendronate sodium tablets)
3 0006-0031-44 1
Apply Prescription Label Here
9508000
WEEK 1
Peel back strip
WEEK 2
Peel back strip
WEEK 3
Peel back strip
WEEK 4
Peel back strip

How to take *Once Weekly* FOSAMAX® 70 mg
(Alendronate Sodium Tablets)

Choose the day of the week that best fits your schedule. Every week, take one FOSAMAX tablet on your chosen day.

After getting up for the day on your chosen day of the week, swallow (do not chew or suck) one FOSAMAX tablet with a full glass (6–8 oz.) of plain water, on an empty stomach. Do not take FOSAMAX at bedtime or before arising for the day.

Begin your morning activities... but don't lie down, eat, drink, or take other medication for at least 30 minutes. If you want to lie down after 30 minutes, you must eat breakfast first.

Remember to take one FOSAMAX tablet once each week on that same day for as long as your doctor prescribes it.

If you miss a dose, take only one FOSAMAX tablet on the morning after you remember. *Do not take two tablets on the same day.* Return to taking one tablet once a week, as originally scheduled on your chosen day.

There is important additional information about how to take *Once Weekly* FOSAMAX in the enclosed Patient Information leaflet. Please read it carefully.

ONCE WEEKLY
FOSAMAX®
(alendronate sodium tablets)

9507900

Choose your day for taking *Once Weekly* FOSAMAX® 70 mg
(Alendronate Sodium Tablets)

Write in the best date for you to start FOSAMAX.

WEEK 1

SUNDAY
MONDAY
TUESDAY
WEDNESDAY

WEEK 2

THURSDAY
FRIDAY
SATURDAY

WEEK 3

How to remove tablets:

1. Peel back strip on back.
2. Push tablet out from front.

WEEK 4

(Time to refill)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Sheldon Markofsky
8/5/02 02:11:31 PM